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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,439	08/23/2001	Herbert H. Hooper	057.01US	4124

33603 7590 06/24/2005

ACLARA BIOSCIENCES, INC.
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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,439	HOOPER ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-11, in the reply filed on 07 April 2003 is acknowledged.

Response to Amendment

2. The amendment filed 15 February 2002 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: The disclosures of the cited documents that "are both incorporated herein by reference in their entirety."

3. Applicant is required to cancel the new matter in the reply to this Office Action.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. The use of the trademark TRITON X-100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

6. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

9. For convenience, claim 1 is reproduced below.

1. A microchannel sample-handling apparatus for processing a sample, comprising

(a) a microchannel device having

(i) a substrate,

(ii) an elongate or planar multisite reaction channel formed in said substrate for receiving a bulk-phase medium containing sample components, said reaction channel having a plurality of reaction regions and region-specific reagents associated with each region, for simultaneously conducted different reactions on sample components within the reaction channel,

(iii) one or more sample-preparation stations in said substrate, upstream of said reaction channel, for carrying out one or more selected sample-preparation steps effective to convert a sample to such bulk-phase medium, and

(iv) one or more product-processing stations downstream of said reaction channel, for processing products generated in one or more of said reaction regions,

means for transferring solvent or solvent components between one of said sample-preparation stations and one or more selected reaction regions in the reaction channel, and between one or more selected reaction regions in the reaction channel and one of said product-processing stations, and

a control unit for activating said transfer means, to effect transfer, in a selected reaction region, of solvent or solvent components from or to each hold or region-specific reservoir, to or from the associated reaction region.

10. For purposes of examination, the claims have been interpreted as encompassing microchannels that can have virtually any depth, width, and length; that volumes and cross sections of the channels are essentially without limit. Additionally, the claims have been interpreted as encompassing virtually an infinite number of reaction regions, that can be spaced at any distance from one another, and wherein virtually any reagent can be applied.

11. A review of the specification, however, fails to locate where the full scope of the clamed invention has been adequately described. Page 9 of the specification, however, has been found to teach that applicant contemplated the channels having a depth of from 20 to 1,000 microns,

have a volume of 25 to 600 nanoliters, and that the channels be spaced 50 to 500 microns apart. Page 11 has been found to provide support for channels having a cross-sectional area of 50 μm^2 to 1 mm^2; that the channels have a length of from about 0.5 cm to about 20 cm. Page 12 has been found support for devices where the reaction volume ranges from about 5 nl to 600 nl, and that the area of the specific binding member ranges from about 10 nm to 5 cm. And page 13 has been found to provide support for distances between confronting channel surfaces ranges from about 20 to 1,000 microns. A review of the disclosure fails to find where applicant had contemplated other depths, volumes, other cross-sectional areas, other lengths, other spacing of channels, and other distances separating confronting channels.

12. Page 17 has been found to provide support for specific binding partners, and that the quantity of any one can range from "at least about 10 attomoles" to "not more than about 1 millimole." A review of the disclosure fails to find where applicant had contemplated other quantities of said specific binding partners, much less reasonably suggests that applicant had possession of an invention that comprised said other quantities.

13. At page 13, first paragraph, the reaction-specific reagent is described further-

> [T]he reagent may be one of a number of different binding agents or drugs, some or all of which are capable of interacting with a receptor carried in the bulk-phase solution, or one of a number of different enzyme substrates, some or all of which are capable of interacting with an enzyme contained in the bulk phase solution, or conversely, one of a number of different proteins or other enzymic or binding agents, some or all of which are capable of reacting with a given substrate or binding agent in the bulk-phase medium. In one preferred embodiment, detailed below, the reagent includes one or more oligo- or poly-nucleotides having a reaction- specific nucleic acid sequence effective to produce a sequence-specific reaction, such as one involving complementary strand hybridization or sequence-specific endonuclease cutting.

A review of the originally filed disclosure finds that there are but 22 sequences listed, and all being DNA oligonucleotides further characterized as being a "probe" or a "primer." The

disclosure has not been found to provide an adequate written description of the infinite number of drugs, binding agents, proteins, enzymes, RNA, DNA, genes, oncogenes, etc., form any and all life forms, the they plant, animal, microbial, viral, prion, etc. In short, the specification does not provide an adequate written description of the various reagents so as to reasonably suggest that applicant, at the time of filing, as in possession of same, much less in possession of a "microchannel sample-handling apparatus" that comprises them.

14. A review of the disclosure fails to find an adequate written description of the "control unit" (claim 10), as well as detachable reaction modules (claim 11), separation channels and devices comprising a plurality of "multisite reaction channels" (claim 9).

15. The disclosure has not been found to provide an adequate written description of the apparatus that further comprises cell culture stations and/or cell lysis, and/or "gated side channels."

16. Rather than provide the requisite, full, clear, and concise description of the invention such that the specification reasonably suggests that applicant had possession of the invention at the time of filing, it appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

17. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

18. It is well settled that one cannot enable that which they do not yet possess. As set forth above, the specification fails to provide the requisite, full, clear, and concise description of the invention such that the specification reasonably suggests that applicant had possession of the invention at the time of filing. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claims 1-11 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US Patent 6,043,080 (Lipshutz et al.).

21. Lipshutz et al., in Figures 3 and 5B, and at columns 2-5, disclose a device that comprises microcapillary channels (applicant's "microchannel") that is in fluid communication with one or more reaction channels having reaction regions that can serve any of a multitude of functionalities, including sample preparation (column 4). At column 5, bridging to column 6 Lipshutz et al., teach the device comprising an array of oligonucleotides (applicant's region-specific reagents"), and that the device can be used in performing various amplification.

22. The aspect of the device comprising means to force fluid from one region/channel to that of another is disclosed at column 2.

23. Column 4, first full paragraph, teaches that the device further comprises controller means for controlling the device and/or obtaining and reading/interpreting the data derived.

24. As seen in Figure 5B, the device may be comprised of a plurality of layers, with channels/chambers being in fluid communication with other such passages found on a different level.

25. In view of the foregoing remarks, claims 1-11 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US Patent 6,043,080 (Lipshutz et al.).

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. US Patent 5,637,469 (Wilding et al.);

b. US Patent 5,674,743 (Ulmer);

c. US Patent 5,866,345 (Wilding et al.); and

d. US Patent 5,992,769 (Wise et al.).

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
21 June 2005